

SEP 26 2005

stryker

K 051741
Howmedica
OSTEONICS

325 Corporate Drive
Mahwah, NJ USA 07430

**510(k) Summary of Safety and Effectiveness for the
Accolade® HFX Femoral Stem**

Proprietary Name: Accolade® HFX Femoral Stem

Common Name: Total Hip Joint Replacement Prosthesis

Classification Name and Reference: Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis,
21 CFR §888.3360

Hip joint, metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prostheses,
21 CFR §888.3353

Regulatory Class: Class II

Device Product Code: 87 KWL - prosthesis, hip, hemi-, femoral, metal

87 LWJ - prosthesis, hip, semi-constrained,
metal/polymer, uncemented

87 LZO - prosthesis, hip, semi-constrained,
metal/ceramic/polymer, cemented or non-porous,
uncemented

For Information contact: Tiffani Rogers
Regulatory Affairs Specialist
Stryker Orthopaedics
325 Corporate Drive
Mahwah, New Jersey 07430
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Date Summary Prepared: June 27, 2005

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Device Description

The Accolade® HFX femoral stem is a tapered cobalt chrome stem. The Accolade® HFX femoral stem is collarless and flat bodied, and will be available in sizes 1 through 8. The proximal body is textured by application of titanium plasma spray to increase the surface area of the stem to accommodate a press-fit fixation.

Intended Use:

The Accolade® HFX hip stem is a single-use, sterile device intended for cementless fixation within the prepared femoral canal.

Indications

- Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed; and,
- Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Substantial Equivalence

The determination of the substantial equivalence of the Accolade® hip stem is based on its similarities in intended use, design and sterilization to the Accolade® TMZF® femoral stem (K994366, cleared March 16, 2000). Predicate device information is located in Appendix E.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Tiffani D. Rogers
Regulatory Affairs Specialist
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K051741
Trade/Device Name: Accolade® Hfx Femoral Stem
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: II
Product Codes: LZO, LWJ, KWL
Dated: June 27, 2005
Received: June 28, 2005

Dear Ms. Rogers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2- Ms. Tiffani D. Rogers

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is fluid and cursive, with a long horizontal stroke at the end.

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051741

Device Name: Accolade® Hfx Hip Stem

Indications

- Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed; and,
- Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Prescription Use X

OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K051741